IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

APOTEX, INC., Plaintiff,	:	CIVIL ACTION
v.	:	No. 2:06-cv-2768
CEPHALON, INC., et al., Defendants.	:	

Goldberg, J. **February 23, 2010**

MEMORANDUM OPINION

This case involves allegations of patent invalidity and infringement. Before the Court is Defendant, Cephalon, Inc.'s "Motion to Dismiss Counts III Through XIII of Plaintiff's Second Amended Complaint," (doc. nos. 157 & 197). For reasons set forth herein, Defendant's Motion will be denied.

I. BACKGROUND

This lawsuit (hereinafter referred to as the Apotex Litigation) is one of several consolidated cases collectively named In re Modafinil.[1] This multi-party litigation emanates from the settlement of a patent infringement suit in late 2005 - early 2006, in the District of New Jersey, between Cephalon, a brand name drug manufacturer, and four (4) generic drug manufacturers (Barr, Mylan,

[1] King Drug Company of Florence, Inc., et al. v. Cephalon, Inc., et al., 2:06-cv-1797 - The King Drug Direct Purchaser Class Action; Vista Healthplan, Inc., et al. v. Cephalon, Inc., et al., 2:06-cv-1833 - The Vista Healthplan End Payor Class Action; Apotex, Inc. v. Cephalon, Inc., et al., 2:06-cv-2768 - The Apotex Litigation; and Federal Trade Commission v. Cephalon, Inc., 2:08-cv-2141 - The F.T.C. Litigation.

Teva and Ranbaxy, hereinafter "the Generic Defendants").[2] The settled patent suit revolved around the proposed sale of a generic version of Provigil®, a sleep disorder drug.[3] The gist of the controversy as it generally pertains to the consolidated cases in In re Modafinil, is that the four (4) settlement agreements in the patent infringement suit constitute unlawful, anti-competitive conduct under the Sherman Antitrust Act, 15 U.S.C. §§ 1, 2.

The Apotex Litigation commenced on June 26, 2006, with the filing of the original Complaint, which raised patent claims regarding Cephalon's RE'516 patent for Provigil® and antitrust claims against Cephalon and the Generic Defendants relating to the settlements noted above. Since that time, the original Complaint has been consolidated with a separate complaint filed by Apotex regarding a second Cephalon patent - '346, also relating to Provigil®. Thereafter, Apotex filed an Amended Complaint and Second Amended Complaint, the latter of which is the subject of the Motion to Dismiss before the Court. As with the original Complaint, Apotex's Second Amended Complaint sets forth patent and antitrust claims.

On January 20, 2010, I granted Apotex's Motion to Bifurcate the patent claims from the antitrust claims. Given the bifurcation, this Opinion will only consider Cephalon's Motion to

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[2] Cephalon v. Mylan Pharm. Inc., et al., No. 2:03-cv-1394 (D.N.J.).

[3] Provigil® is a prescription drug used to promote wakefulness in adults with sleep disorders such as shift work disorder, obstructive sleep apnea and narcolepsy. The Generic Defendants originally asserted that they had non-infringing generic versions of Provigil® which they intended to market. The settlements ultimately reached in the underlying patent infringement case prohibited the Generic Defendants from selling generic versions of Provigil®. (Apotex Second Am. Comp., ¶¶ 39, 51, 147.)

Dismiss as it relates to the declaratory judgment patent claims, Counts III - V.[4] Thus, the patent claims currently at issue are: Count (III) declaratory judgment for non-infringement of the RE'516 patent against Cephalon; Count (IV) declaratory judgment for patent invalidity of the '346 patent against Cephalon; and Count (V) declaratory judgment for non-infringement of the '346 patent against Cephalon.

Cephalon has moved to dismiss Count III, non-infringement of the RE'516 patent, arguing that there are no allegations set forth in the Complaint as to why the RE'516 patent is not infringed. Cephalon further asserts that Count III is impermissibly redundant with Count I (invalidity of the RE'516 patent). Cephalon also seeks dismissal of Counts IV and V claiming that Apotex lacks standing to bring a declaratory judgment action on the '346 patent because there is no case and controversy regarding the '346 patent, due to the fact that a declaratory judgment on the RE'516 patent is enough to trigger the 180-day market exclusivity under the Hatch-Waxman Act for the Generic Defendants.

Apotex generally responds that it has pled with sufficient specificity as to how its generic product, Abbreviated New Drug Application (hereinafter "ANDA") 77-667, does not infringe upon the RE'516 patent. They also argue that the Court has jurisdiction to hear the declaratory judgment claims on the '346 patent, because there is a case and controversy.

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[4] Cephalon has not moved to dismiss Counts I & II of Apotex's Second Amended Complaint. Cephalon's Motion to Dismiss the antitrust claims is currently pending before this Court.

II. ANALYSIS - MOTION TO DISMISS COUNT III (NON-INFRINGEMENT OF THE RE'516 PATENT)

A. Legal Standard - Motion to Dismiss For Failure to State a Claim Upon Which Relief Can Be Granted

A motion to dismiss under FED. R. CIV. P. 12(b)(6) for failure to state a claim upon which relief can be granted examines the legal sufficiency of the complaint. Conley v. Gibson, 355 U.S. 41, 45-46 (1957). FED. R. CIV. P. 8(a)(2) requires that a pleading contain a "short and plain statement of the claim showing that the pleader is entitled to relief." According to the Supreme Court, the Rule 8 pleading standard "does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). The Iqbal Court recently summarized the pleading standard established in Twombly:

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

Iqbal, 129 S.Ct. at 1949 (citations omitted).

The Iqbal Court articulated two (2) principles that underlie Twombly's holding. First, a court must accept as true all of the factual allegations made in a pleading, but not the legal conclusions. Id. Second, only a complaint that states a "plausible claim for relief survives a motion to dismiss." Id. at 1950. Determining plausibility is a "context specific task." Id. In short, "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the

complaint has alleged-but it has not shown-that the pleader is entitled to relief." Id. (citations omitted). The Third Circuit has found that in light of Twombly, it is no longer sufficient to make an unsupported statement asserting an entitlement to relief; instead, a complaint must state a claim and the grounds supporting the claim. Phillips v. County of Allegheny, 515 F.3d 224, 233-34 (3d Cir. 2008) (citing Twombly, 127 S.Ct. at 1969 n.8).

B. Allegations Set Forth in the Second Amended Complaint

As noted above, Cephalon claims that Count III, non-infringement of the RE'516 patent, is impermissibly redundant with Count I, which alleges invalidity of the RE'516 patent. Cephalon also argues that Apotex has not pled any specific allegations supporting its claim of non-infringement. (Def. Memo., pp. 49-50.)

In addressing the distinction between invalidity and non-infringement claims, the Federal Circuit explained that:

> Though an invalid claim cannot give rise to liability for infringement, whether it is infringed is an entirely separate question capable of determination without regard to its validity. Because both validity and infringement involve construction of a claim, and because the construction must be the same in determining both, it is desirable to decide both questions at the same time.

Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1583 (Fed. Cir. 1983). This precedent suggests that not only are claims of invalidity and non-infringement not redundant, but that such claims should be litigated at one (1) time.

Regarding the sufficiency of the Complaint, Apotex has pled that its generic product, ANDA 77-667, does not infringe on the RE'516 patent, because their product does not contain "95% of the cumulative total modafinil particles having a diameter of less than about 200 microns," which is the claim of the RE'516 patent. (Apotex Second Am. Comp., ¶ 216.) As noted previously, at this stage

of litigation these allegations must be accepted as true. Iqbal, 129 S.Ct. at 1949. Viewed in this light, Apotex's Second Amended Complaint states a plausible claim for relief. Accordingly, we find that Apotex's invalidity and non-infringement claims are not redundant, and that Apotex has stated a claim upon which relief can be granted.

III. ANALYSIS - MOTION TO DISMISS COUNTS IV & V (INVALIDITY & NON-INFRINGEMENT OF THE '346 PATENT)

A. Legal Standard - Motion to Dismiss For Lack of Subject Matter Jurisdiction

Cephalon also seeks the dismissal of Counts IV and V, invalidity of the '346 patent and non-infringement of the '346 patent, asserting a lack of subject matter jurisdiction because Apotex lacks standing in that there is no case or controversy.

The standard for a motion to dismiss for lack of subject matter jurisdiction under FED. R. CIV. P. 12(b)(1) in the declaratory judgment context is governed by MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118 (2007). The Declaratory Judgment Act's phrase "actual controversy" "refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III." Id. at 127. The MedImmune Court explained that:

> [T]he dispute [must] be "definite and concrete, touching the legal relations of the parties having adverse legal interests"; and that it be "real and substantial" and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical set of facts."

Id. (citing Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240 (1937)). The Court found that the correct standard for determining whether there is a justiciable case or controversy is "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of

a declaratory judgment." Id. (citing Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941)).

More specifically, declaratory judgment jurisdiction under 28 U.S.C. § 2201, which is at issue here, extends to ANDA Paragraph IV disputes under 35 U.S.C. § 271(e)(5) to the extent consistent with the Constitution - when there is a "case" or "controversy." Teva Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330, 1336 (Fed. Cir. 2007).

In an Article III action, the plaintiff must have standing, the issue before the court must be ripe for decision, and the case must not be moot. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). A plaintiff has standing where there is an injury-in-fact, the causation of that injury is traceable to the defendant's alleged conduct, and there is redressability for that injury through the requested relief. Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 102-03 (1998). A case is ripe when the issues are fit for judicial decision and withholding court consideration would be a hardship to the parties. Abbott Labs. v. Gardner, 387 U.S. 136, 149 (1967). A case is moot when the parties no longer have a cognizable legal interest in the outcome. U.S. Parole Comm'n v. Geraghty, 445 U.S. 388, 397 (1980).

B. Allegations Set Forth in the Second Amended Complaint

In support of its position that there is no controversy before the Court, Cephalon notes that its settlement agreements with the Generic Defendants allow market entry of a generic version of Provigil® upon a declaratory judgment of invalidity of the RE'516 patent. Cephalon explains that if the RE'516 is declared invalid, the Generic Defendants will enter the market and the 180-days of market exclusivity under the Hatch-Waxman Act will be triggered, allowing Apotex to enter with its generic version of Provigil®, ANDA 77-667, on day 181. Thus, Cephalon concludes that Apotex does not need a declaratory judgment on the '346 patent to enter the market because their claims

under the RE'516 patent will accomplish this, so there is no case or controversy. (Def. Memo., pp. 49-50.)

Apotex disagrees and maintains that because the '346 patent was listed in the Orange Book[5] along with the RE'516 patent for Provigil®, a declaratory judgment is needed on both patents to obtain FDA approval of its ANDA. Apotex also stresses that they are entitled to obtain patent certainty on both patents. (Pl. Memo., pp. 51-59.)

Cephalon concedes that there is subject matter jurisdiction under Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1291 (Fed. Cir. 2008), regarding a subsequent ANDA filer's declaratory judgment on a patent, even when there is no threat of a patent infringement suit, where the patent is a barrier to market entry and a favorable judgment would remove that barrier. (Def. Memo., p. 41 n. 20.) Cephalon posits, however, that such jurisdiction is only appropriate as to the RE'516 patent, because, given the settlement agreements between Cephalon and the Generic Defendants in the underlying litigation, a favorable judgment on the RE'516 patent alone will remove the barrier to market entry. (Def. Memo., pp. 46-48.) Apotex contests such a reading of the settlement agreements and asserts that the agreements require entry of another modafinil generic (not one (1) of the Generic Defendants) to allow the Generic Defendants to enter the market. (Pl. Memo., pp. 56-57.)

As a backdrop to sorting out the parties' respective arguments, it is important to emphasize that this matter is still at the pleading stage, without a fully developed record, particularly regarding the settlement agreements with the Generic Defendants. Given the factual disagreement as to what

[5] The "Approved Drug Products With Therapeutic Equivalence Evaluations" is the publication in which the FDA lists all patents and is commonly known as the "Orange Book." (Apotex Second Am. Comp., ¶ 45.)

effect a judgment of non-infringement on the RE'516 patent will have on Apotex's ability to enter the market, and because all allegations in the Second Amended Complaint must be accepted as true for the purposes of the Motion to Dismiss, Apotex's interpretation of the settlement agreements must be given deference. Therefore, Apotex may pursue a declaratory judgment of patent invalidity and/or non-infringement for both the RE'516 and '346 patents. This decision is appropriate for additional reasons.

As with the generic drug company's standing in Caraco, 527 F.3d 1278, Apotex has met the Constitutional standards for standing on the '346 patent. As in Caraco, there is an injury-in-fact because Apotex alleges that it has been excluded from selling a product that is not subject to a valid patent, or if the patent is valid, excluded for selling a non-infringing product because Cephalon's settlement agreements with the Generic Defendants prevent Apotex from obtaining FDA approval on its ANDA. See id. at 1291; see also, Novartis, 482 F.3d at 1340. Apotex's injury may be traceable to Cephalon's actions and is not simply a function of the Hatch-Waxman framework. Because Apotex needs a favorable judgment on both the RE'516 and '346 patents in order to enter the market, Apotex's injury-in-fact is redressible by a declaratory judgment. See Caraco, 527 F.3d at 1293.

In addition, we have also weighed other factors (e.g., "all the circumstances," MedImmune, 549 U.S. at 127), as they relate to whether there is a controversy in Apotex's declaratory judgment action on the '346 patent. The factors considered include the following:

First, Cephalon could sue Apotex for patent infringement on both the RE'516 and '346 patents under 35 U.S.C. § 271 (e)(2)(A), because "submitting an ANDA regardless of how many paragraph IV certifications it may contain, is a single act of infringement." Novartis, 482 F.3d at

1340. "It logically follows that if such an action creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party." Id. at 1342. Thus, in considering the totality of the circumstances, it is immaterial in a declaratory judgment action, which party "started" the litigation. Md. Cas. Co., 312 U.S. at 273.

Second, the Novartis Court has noted that: (1) the civil action to obtain patent certainty under 21 U.S.C. § 355(j)(5)(c); (2) the ANDA declaratory judgment provision under 35 U.S.C. § 271(e)(5); and (3) the purpose of the Hatch-Waxman Act, all create a case and controversy, and are relevant considerations under the totality of the circumstances test. Novartis, 482 F.3d at 1342-43.

Third, Apotex challenged the validity of Cephalon's patent for Provigil® and/or claimed non-infringement when it filed Paragraph IV certifications for both the RE'516 and '346 patents. Similar to how that act of infringement creates a controversy on which Cephalon could, but chose not to, sue Apotex for infringement on the RE'516 patent, Apotex also created an actual controversy regarding the '346 patent by placing in dispute its validity and/or non-infringement. While the '346 and RE'516 patents are different "patent cases," they arise out of the same controversy - whether Apotex can market its ANDA. Where two (2) patents relate to the same controversy between an ANDA and a New Drug Application, that factor can be considered in the totality of the circumstances as to whether there is a justiciable controversy. Id. at 1341-42.

Lastly, Apotex's pending RE'516 patent declaratory judgment action is also a factor in considering "all of the circumstances." Apotex is left with uncertainty regarding its ANDA if it may only proceed on the RE'516 patent and not the '346 patent. Indeed, both patents are listed in the Orange Book for Provigil®. In non-ANDA cases, litigation involving the same technology and the same parties is relevant in determining whether there is a justiciable controversy on related patents,

and that same logic applies in the ANDA context. Id. at 1344-45 (citing Vanguard Research, Inc. v. PEAT, Inc., 304 F.3d 1249, 1255 (Fed. Cir. 2002)). Put another way, the possibility of future litigation on the same ANDA is a "circumstance" which weighs in favor of finding that Apotex has alleged facts establishing a case or controversy. If Apotex wins its declaratory judgment action on the RE'516 patent and goes to market with its generic version of Provigil®, then Apotex could still, at any time, be subject to a patent infringement suit by Cephalon on the '346 patent. This threat of future protracted litigation, which clearly relates to the current litigation, is a factor weighing against Cephalon in the resolution of this motion.[6] Id. at 1345.

Finally, we also reject Cephalon's argument that Counts IV and V are not properly pled. (Def. Memo., pp. 48-49.) As to Count IV, invalidity of the '346 patent, Apotex has alleged, and we must accept as true, that the '346 patent is invalid because of the on-sale bar which violates 35 U.S.C. §§ 102, 103 and/or 112. (Apotex's Second Am. Comp., ¶ 228.) As to Count V, non-infringement of the '346 patent, Apotex has alleged, and we must accept as true, that its product, ANDA 77-667, does not infringe on the '346 patent because it does not contain the same concentration of modafinil as protected by the '346 patent.[7] (Apotex's Second Am. Comp., ¶ 235; Pl. Memo., p. 58.) These allegations contain sufficient factual matter to state a plausible claim for relief.

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[6] The Federal Circuit has found that this threat of future litigation is a factor to be considered even when the name-brand company offers the generic company a covenant not to sue on the second, yet to be litigated, patent listed for an ANDA. Id. at 1296-97.

[7] We also note that Cephalon received a Notice Letter from Apotex pursuant to 21 U.S.C. § 355(j)(2)(B), which sets forth the "detailed statement of the factual and legal basis of the opinion of the applicant [Apotex] that the ['346] patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B). (Pl. Memo., p. 58 n. 26.)

IV. ANALYSIS - STRIKING PRAYER FOR RELIEF (e)

Lastly, Cephalon has moved to strike Apotex's prayer for relief which seeks the delisting of the RE'516 Patent from the Orange Book. Cephalon contends that such relief is improper under Hatch-Waxman, which limits delisting as a relief only available in counterclaims to a Paragraph IV patent infringement suit. (Def. Memo, p. 40.) The Federal Circuit, however, has held that, "as part of its inherent power to give effect to a judgment, a court may order the delisting of a patent in the context of a properly filed patent infringement suit." Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1333 (Fed. Cir. 2001) (noting that delisting is not a separate cause of action). Therefore, Apotex's prayer for relief (e) will not be stricken.

V. CONCLUSION

For the reasons outlined herein, Cephalon's Motion to Dismiss as to Counts III, IV & V of Apotex's Second Amended Complaint is denied.

Our Order follows.